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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,524	07/07/2006	Per Munk Nielsen	10578-US-PCT	7930

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NOVOZYMES NORTH AMERICA, INC.
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EXAMINER

WILLIAMS, LELA

ART UNIT	PAPER NUMBER
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1789

NOTIFICATION DATE	DELIVERY MODE
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03/08/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

Office Action Summary	Application No. 10/585,524	Applicant(s) NIELSEN, PER MUNK	
	Examiner LELA S. WILLIAMS	Art Unit 1789	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-14 and 17-21 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-14 and 17-21 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Applicant's amendment filed on December 6, 2011 has been fully considered. The amendment is not persuasive; therefore, the following action is made FINAL.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claim 1, 3, 5, 6, 7, 11, 14, 17, 18, 19, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al CH Patent No. 356,659.**

Winterbottom et al. discloses a method for producing a food product which comprises contacting meat with a solution containing lactobionic acid (pg. 2, lines 15-20 & pg. 3, line 24, pg. 4, line 16). Slaughtered poultry was submerged into the lactobionic acid containing solution, for a time of 30 minutes to 4 hours (marinate), and allowed to freeze; the poultry was then packed and distributed to the market place (pg.1, lines 26-31 & pg. 5, lines 18-22). Winterbottom also discloses the poultry will be cooked (pg. 5, line 9), therefore becoming heated.

Although Winterbottom discloses that the flesh of the poultry "absorbs sufficient antibiotic matter to guarantee adequate protection" (pg. 6, line 24-26), the reference does not expressly disclose the amount of lactobionic acid absorbed or that the amount was "sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid". However, given the references disclosure of "sufficient" amount was absorbed; it is clear, absent any clear and convincing evidence to the contrary, that said sufficient amount would include 0.1-20% and which would have been "sufficient to reduce the water loss upon freezing

Art Unit: 1789

and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”.

Furthermore, given that the product of claims 1, 19, 20, and 21 depends on the infusing process; it would have been within the ambit of one of ordinary skill to proceed with the infusion process until the meat contains the desired weight percentage of each component, to include 0.1-20% lactobionic acid. Winterbottom teaches the antibiotic solution should be present in amounts to have the “desired and recommended efficacy” (p. 2, lines 14) and the added acid presents no foam formation, cloudiness, or precipitate after the solution was laid to rest in water (page 2, line 30) and the acid should not be able to prevent the loss of antibiotic in the solution (p. 3, line 10). Winterbottom states the quantity of the antibiotic agent would also depend on cost (p. 5, line 11) and flesh poultry was soaked for a time to absorb sufficient antibiotics and to guarantee adequate protection (p. 5, line 25). As such, one of ordinary skill in the art at the time of the invention having adequate financial means and skill set would determine the time required for the process to be performed and the appropriate amount of lactobionic acid needed to avoid formation of foam, cloudiness, or precipitate but also determine the amount needed to be absorbed by the poultry to provide the desired and recommended efficacy. In addition, since the product of claims 14, 17, 18 depend on variables which can be modified, such as cost, length of time of infusion and temperature, and the amount of components used in preparing the stock solution, which Winterbottom discloses would vary because cost of the constituents was a “major factor” (col. 3, lines 72-75); one of ordinary skill in the art would easily determine acceptable amounts, including those which are presently claimed, through routine experimentation. As such, as set

Art Unit: 1789

forth in MPEP§2144.05, discovering an optimum value of a result effective variable, involves only routine skill in the art and would not warrant patentability.

4. Claims 1, 3, 5, 6, 7, 11, 14, 17, 18, 19, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable by Winterbottom et al. U.S Patent No. 2,930,702.

Winterbottom et al. discloses a method for producing a food product which comprises contacting meat with lactobionic acid (col. 1, line 15, col.2, line 10, & col. 3, line 1). Slaughtered poultry was submerged into an antibiotic solution containing lactobionic acid (col. 3, line 34) and allowed to freeze for at least 30 minutes, after which, the poultry was then packed and distributed to the market place (col.4, lines 6-15). The poultry will be cooked (col. 3, line 70), therefore becoming heated.

Although Winterbottom discloses that the flesh of the poultry “absorbs sufficient antibiotic matter to guarantee adequate protection” (pg. 6, line 24-26), the reference does not expressly disclose the amount of lactobionic acid absorbed or that the amount was “sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”. However, given that the poultry was soaked for at least 30 minutes in the lactobionic acid containing solution, and the references disclosure of a sufficient amount was absorbed; it is clear, absent any clear and convincing evidence to the contrary, that said sufficient amount would include 0.1-20% and would be “sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”.

Art Unit: 1789

Furthermore, given that the product of claims 1, 19, 20, and 21 depends on the infusing process; it would have been within the ambit of one of ordinary skill to proceed with the infusion process until the meat contains the desired weight percentage of each component, to include 0.1-20% lactobionic acid. Winterbottom teaches the antibiotic solution should be present in amounts to have the “desired and recommended efficacy” (p. 2, lines 14) and the added acid presents no foam formation, cloudiness, or precipitate after the solution was laid to rest in water (page 2, line 30) and the acid should not be able to prevent the loss of antibiotic in the solution (p. 3, line 10). Winterbottom states the quantity of the antibiotic agent would also depend on cost (p. 5, line 11) and flesh poultry was soaked for a time to absorb sufficient antibiotics and to guarantee adequate protection (p. 5, line 25). As such, one of ordinary skill in the art at the time of the invention having adequate financial means and skill set would determine the time required for the process to be performed and the appropriate amount of lactobionic acid needed to avoid formation of foam, cloudiness, or precipitate but also determine the amount needed to be absorbed by the poultry to provide the desired and recommended efficacy. In addition, since the product of claims 14, 17, 18 depend on variables which can be modified, such as cost, length of time of infusion and temperature, and the amount of components used in preparing the stock solution, which Winterbottom discloses would vary because cost of the constituents was a “major factor” (col. 3, lines 72-75); one of ordinary skill in the art would easily determine acceptable amounts, including those which are presently claimed, through routine experimentation. As such, as set forth in MPEP§2144.05, discovering an optimum value of a result effective variable, involves only routine skill in the art and would not warrant patentability.

Art Unit: 1789

5. Claims 2, 8-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al. CH Patent No. 356,659 or Winterbottom et al. U.S Patent No. 2,930,702 in view of Roselle et al. U. S. Pat. No. 6,773,737.

Winterbottom is applied as discussed above in paragraphs 4 and 5. Both references were silent to applying lactobionate acid to minced, fish, or emulsified meat and the product being surimi. Both are also silent to the form of lactobionate acid.

Roselle discloses a method for treating food products with a solution containing calcium lactobionate (col. 1, line 45 & col. 6, line 63). The food product can be in the form of beef, pork, chicken, and shellfish. Ground (minced) beef or turkey and fish cakes (of which surimi would be consider since it is defined as "ground meat") and fish cakes are also disclosed, as well as emulsified meat product, such as bologna, hot dogs, and sausages (col. 11, lines 3-10).

Therefore, it would have been obvious to one of ordinary skill in the art to use a solution containing calcium lactobionate in minced meat or surimi, as disclosed by Roselle, in Winterbottom, given Roselle's teaching of the solution being effective in killing microorganisms in food (col. 10, lines 21-53).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al. CH Patent No. 356,659 or Winterbottom et al. U.S Patent No. 2,930,702 in view of Halden et al. EP 0 354 262.

Winterbottom discloses treating a food product with a lactobionic acid containing solution, resulting in a meat product containing lactobionic acid. The references were silent concerning marinating the meat by tumbling, however given that Halden teaches marinating

Art Unit: 1789

meat using tumbling procedures (pg. 2, line 26) along with tumbling being a well-known procedure in the art, it would have been obvious to one of ordinary skill to use said procedure since it was known to allow for more penetration of the desired marinade (pg. 2, line 32).

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterbottom et al. CH Patent No. 356,659 or U.S Patent No. 2,930,702 in view of Hayashabira GB Patent No. 1 325 727.

Winterbottom et al. discloses treating a food product with a lactobionic acid containing solution, resulting in a meat product containing lactobionic acid. The references were silent concerning how the lactobionic acid was produced. Hayashabira discloses producing lactobionic acid from lactose by enzymatic oxidation (pg. 1, lines 71-85). Therefore, it would have been within the ambit of one of ordinary skill to manufacture said acid enzymatically given it is a known formation source in the art.

Response to Arguments

8. Regarding applicants remarks to Winterbottom not disclosing the presently claimed amounts of lactobionic acid, Winterbottom discloses that the flesh of the poultry “absorbs sufficient antibiotic matter to guarantee adequate protection” (pg. 6, line 24-26). It is noted that the reference does not expressly disclose the amount of lactobionic acid absorbed or that the amount was “sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”. However, given that the poultry is soaked for at least 30

Art Unit: 1789

minutes in the lactobionic acid containing solution, and the references disclosure of a sufficient amount is absorbed; it is clear, absent any clear and convincing evidence to the contrary, that said sufficient amount would include 0.1-20% and would be “sufficient to reduce the water loss upon freezing and subsequent thawing of the meat based food product by 2% or more compared to the water loss of a similar food product prepared without lactobionic acid”.

Furthermore, given that the product of claims 1, 19, 20, and 21 depends on the infusing process; it would have been within the ambit of one of ordinary skill to proceed with the infusion process until the meat contains the desired weight percentage of each component, to include 0.1-20% lactobionic acid. Winterbottom teaches the antibiotic solution should be present in amounts to have the “desired and recommended efficacy” (p. 2, lines 14) and the added acid presents no foam formation, cloudiness, or precipitate after the solution was laid to rest in water (page 2, line 30) and the acid should not be able to prevent the loss of antibiotic in the solution (p. 3, line 10). Winterbottom states the quantity of the antibiotic agent would also depend on cost (p. 5, line 11) and flesh poultry was soaked for a time to absorb sufficient antibiotics and to guarantee adequate protection (p. 5, line 25). As such, one of ordinary skill in the art at the time of the invention having adequate financial means and skill set would determine the time required for the process to be performed and the appropriate amount of lactobionic acid needed to avoid formation of foam, cloudiness, or precipitate but also determine the amount needed to be absorbed by the poultry to provide the desired and recommended efficacy. In addition, since the product of claims 14, 17, 18 depend on variables which can be modified, such as cost, length of time of infusion and temperature, and the amount of components used in preparing the stock solution, which Winterbottom discloses would vary because cost of the constituents was a “major factor”

Art Unit: 1789

(col. 3, lines 72-75); one of ordinary skill in the art would easily determine acceptable amounts, including those which are presently claimed, through routine experimentation. As such, as set forth in MPEP§2144.05, discovering an optimum value of a result effective variable, involves only routine skill in the art and would not warrant patentability.

Applicant's statement with Winterbottom regarding soaking the solution for 30 minutes in 3-30% lactobionic acid is correct. Winterbottom states the compound contains 3-30% lactobionic acid and said compound was diluted to obtain the dip solution. However, given that Winterbottom states the amount of the acid will vary for reasons such as cost, foam formation/cloudiness, etc., and loss of antibiotic; and the references disclosure of "sufficient" amount was absorbed; it is clear, absent any clear and convincing evidence to the contrary, that said sufficient amount would include 0.1-20%; as it would have been within the ambit of one of ordinary skill in the art that the time of the invention to determine the appropriate amount of lactobionic acid needed for adequate absorption of the poultry. One of ordinary skill in the art, with adequate financial means, would have been motivated to infuse the poultry with the solution containing lactobionic acid, for a time suitable for the meat to absorb sufficient amounts of each component, including that presently claimed, in efforts to prolong the shelf life of the product.

In response to applicant's argument that the purpose of added lactobionic acid in Winterbottom teaches away from the present invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Given that Winterbottom discloses contacting meat with a solution containing lactobionic acid, as presently claimed, the

Art Unit: 1789

references meets the presently claimed limitation. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., applying acid alone to the meat) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's argument regarding Halden (EP 0 354 262), Hayashabira (GB 1 325 727) and Roselle (US 6,773,737) have been noted, and note that while Halden (EP 0 354 262), Hayashabira (GB 1 325 727) and Roselle (US 6,773,737) do not disclose all the features of the present claimed invention, they are used as a teaching references, and therefore, it is not necessary for these secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather these references teaches a certain concept, marinating meat using a tumbling procedure (Halden); producing lactobionic acid from lactose by enzymatic oxidation (Hayashabira); teaching a solution of calcium lactobionate being effective in killing microorganisms in food (Roselle); and in combination with the primary reference, discloses the presently claimed invention.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1789

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LELA S. WILLIAMS whose telephone number is (571)270-1126. The examiner can normally be reached on Monday to Thursday from 7:30am-5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Humera Sheikh can be reached on 571-272-0604. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/585,524

Page 12

Art Unit: 1789

/LELA S WILLIAMS/
Examiner, Art Unit 1789

/Kelly Bekker/

Primary Examiner